K061727

AUG - 7 2006

SUMMARY OF 21 CFR 807.87

Proprietary Name:	GORE PRECLUDE® Vessel Guard
Common Name:	Vessel Guard
Classification Name:	
Device Classification:	Class II
Product Classification and Code:	MFX
Classification Panel:	Cardiovascular Devices

Establishment Registration Number: 2017233

Contact Person: Michael Ivey
Regulatory Affairs
Medical Products Division
W. L. Gore & Associates, Inc.
3450 West Kiltie Lane
Flagstaff, AZ 86002-0500

Telephone: (928) 864-3790
Facsimile: (928) 779-3480
E-mail: *mivey@wlgore.com*

Performance Standards

Performance standards do not currently exist for these devices. None are established under Section 514.

Device Manufacturer

W. L. Gore & Associates, Inc.
3750 West Kiltie Lane
Flagstaff, AZ 86002-0500
Establishment Registration Number: 2017233

Device Sterilizer

W.L. Gore and Associates
1500 N. Fourth Street.
Flagstaff, AZ 86001
Establishment Registration Number: 2017233

Purpose of Submission

The purpose of this 510(k) Premarket Notification submission is to propose a new indication for the GORE ACUSEAL Cardiovascular Patch (previously cleared under K984526 April 8, 1999).

This new indication (shown below) would be marketed under the name **GORE PRECLUDE® Vessel Guard.**

Indication for Use

The new indication for use is identified below.

> The GORE PRECLUDE® Vessel Guard is indicated as a cover for vessels following anterior vertebral surgery to reduce the risk of potential vessel damage during a revision surgery by providing a plane of dissection.

510(k) Summary of Substantial Equivalence

In response to the requirements addressed by the Safe Medical Device Act of 1990, a 510(k) summary of the information upon which the substantial equivalence determination is based may be found in the 510(k) Summary of Substantial Equivalence section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2006

W.L. Gore & Associates, Inc.
c/o Mr. Michael Ivey
Regulatory Affairs
3450 West Kiltie Lane
P.O Box 2400
Flagstaff, AZ 86003-2400

Re: K061727
GORE PRECLUDE® Vessel Guard
Regulation Number: (not classified)
Regulation Name: pericardial patch
Regulatory Class: III (three)
Product Code: MFX
Dated: June 16, 2006
Received: June 19, 2006

Dear Mr. Ivey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but **not** limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): ~~TBD~~ → K061727

Device Name: GORE PRECLUDE® VESSEL GUARD

Intended Use / Indication For Use: The GORE PRECLUDE® Vessel Guard is indicated as a cover for vessels following anterior vertebral surgery to reduce the risk of potential vessel damage during a revision surgery by providing a plane of dissection.

Prescription Use X (Part 21 CFR 801 Subpart D) AND OR Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061727